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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,837	10/23/2001	David Stern	3371.1	9174

22886 7590 08/08/2003

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/682,837	STERN, DAVID	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2003 and 17 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>0303</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

FINAL ACTION

1. This action is in response to papers filed 17 January 2003 in which the first paragraph of the specification was amended, non-elected Claims 1 and 21-35 were canceled and the previous rejection was discussed. This action is further in response to papers filed 17 March 2003 in which the first paragraph of the specification was further amended, a petition to correct inventorship was filed and Statements under 1.48(a)(2) by Richard Rava and under 1.48(a)(5) by Barbara Caulfield were filed.

The previous rejections in the Office Action dated 17 September 2002 are maintained. All of the arguments have been thoroughly reviewed and are discussed below.

Claims 2-20 are under prosecution.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

a. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

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As set forth in the previous Office Action of 17 September 2002, Rava et al (U.S. Patent No. 5,545,531) does not teach the limitations of Claim 4 and 13-15. Therefore, the subject matter of Claims 4 and 13-15 are not supported the '531 patent. Because the '531 does not provide support for instant Claims 4 and 13-15, the '531 patent does not meet the requirements under 35 U.S.C. 112 for a continuation parent as instantly claimed. Therefore, Applicant's amendment to the specification stating that the instant application is a continuation of the '531 patent constitutes new matter. As such, the amendment is objected to under 35 U.S.C. 112, first paragraph, new matter.

It is further noted that in papers filed 22 January 2003, Applicant states that the '531 patent does not teach all the limitations of claims 2, 3, 5-12 and 16-20. This suggests that Applicant acknowledges that the instant application is not a continuation of the '531 patent.

b. The amendment filed 17 March 2003 is further objected to because it states that the instant application (filed 10/23/2001) is a continuation of application 10/157,252, filed 28 May 2002. However, an application cannot be a continuation of a later filed application (37 C.F.R. 1.53(d)). Because the '252 application was filed after the instant application, the instant application cannot be a continuation of the '252 application.

c. The amendment filed 17 March 2003 is further objected to because the amendment do not comply with the requirements for filing a priority claim as set forth in 37 C.F.R. 1.78(a).

This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four

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months from the date on which the national stage commenced under 35 U.S.C. 371 (b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application.

d. For all the reasons stated above, the amendment to the specification filed 17 March 2003 is objected to.

Appropriate correction is required.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it does not list the parent applications to which Applicant is claiming priority.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2, 3, 5-12 and 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Rava et al (U.S. Patent No. 5,545,531, issued 13 August 1996).

Regarding Claim 2, Rava et al disclose scanning system for scanning a plurality of microarray disposed on a substrate comprising: a scanner apparatus constructed and arranged to detect emission signals from the substrate; a convertible processing apparatus (x-y-z table) including a containing member (i.e. holder) constructed and arranged to contain the substrate and a separating member (i.e. body containing channels which forms wells when placed on the substrate) which is constructed and arranged so that when the separating member is disposed in a first position (i.e. on the substrate) with respect to the containing members, at least two of the microarrays are fluidically separated from each other by the separating member and when the separating member is in a second position with respect to the containing members the at least two arrays are fluidically coupled with each other (Column 5, lines 16-65) wherein the substrate comprises a plurality of microarrays (Column 8, lines 1-5).

Regarding Claim 3, Rava et al disclose the scanner apparatus comprises an excitation radiation source; a focusing system constructed and arranged to focus radiation from the excitation source onto a selected first portion of the substrate; a radiation direction system constructed and arranged to scan the focused excitation radiation across the first portion of the substrate; a detector constructed and arranged to detect the emission signals from the first portion of the substrate in response to focused excitation radiation; and a data acquisition

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system constructed and arranged to record an amount of the emission signals detected as a function of the positions on the substrate (Column 6, line 34-Column 7, line 27).

Regarding Claim 5, Rava et al disclose the system wherein the radiation direction system includes a mirror selected from a galvanometric mirror and rotating polyhedral mirror (Column 6, lines 47-51).

Regarding Claim 6, Rava et al disclose the system wherein the focused excitation radiation is reciprocally scanned across a second portion of the substrate including at least two of the microarrays at a rate of at least 20 image lines per second i.e. each well comprising an array is read in less than 5 seconds (Column 6, lines 63-67).

Regarding Claim 7, Rava et al disclose the system wherein the data acquisition system includes a computer having a processor and a memory wherein the computer is constructed and arranged to receive image data representing the detected emission signals from the scanner apparatus and to store the image data in the memory (Column 6, lines 34-51 and Column 7, lines 4-12).

Regarding Claim 8, Rava et al disclose the system wherein the computer when executing a scanner control, data acquisition, and data analysis application is further constructed and arranged to control the focusing system and radiation direction system so as to sequentially focus on and irradiate a first of at least two microarrays and then sequentially focus on and irradiate one or more other microarrays (Column 5, lines 57-65).

Regarding Claim 9, Rava et al disclose the apparatus wherein the convertible processing apparatus is coupled to a translation stage; and the scanner apparatus further comprises a translation stage controller constructed and arranged to move the translation stage under the direction of the computer in coordination with the focusing system and radiation direction system (Column 5, lines 57-65).

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Regarding Claim 10, Rava et al disclose the system wherein the translation stage controller moves the translation stage in an x direction and a y direction to sequentially position each of the microarrays for irradiation (Column 5, lines 25-29 and 57-65).

Regarding Claim 11, Rava et al disclose the system wherein x and y are orthogonal to each other (Column 5, lines 25-29 and 57-65).

Regarding Claim 12, Rava et al disclose the system wherein the translational stage controller moves the translation stage in a z direction orthogonal to a plane of the x and y so as to sequentially position each of the plurality of microarrays (Column 5, lines 25-29 and 57-65).

Regarding Claim 16, Rava et al disclose the system wherein the separating member includes one or more walls (i.e. channel walls) constructed and arranged to fluidically separate the at least two microarrays when the separating member is disposed in the first position (Column 8, lines 1-21).

Regarding Claim 17, Rava et al disclose the system wherein the separating member includes a grid plate (i.e. the body comprises a grid-like arrangement of channels, see Fig. 4) wherein the grid plate includes a plurality of grid elements (i.e. channels) determined by the one or more walls wherein each of the microarrays is fluidically separated from each of the other microarrays by a grid element when the separating member is disposed in the first position (on the substrate) and wherein each of the microarrays is fluidically coupled with each other when the separating member is in the second position (i.e. off the substrate before and/or after placing the body on the substrate)(Column 8, lines 1-21 and Fig. 4).

Regarding Claim 18, Rava et al disclose the system wherein the plurality of grid elements is equal in number to the plurality of microarrays i.e. "the walls of the channels are placed on the wafer so that each surrounds and encloses the probe array" (Column 8, lines 9-11).

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Regarding Claim 19, Rava et al disclose the system wherein the microarrays include synthesized probe arrays wherein the probe comprise oligonucleotides (Column 9, lines 10-27 and Column 10, lines 16-23).

Regarding Claim 20, Rava et al disclose the system wherein the plurality of microarrays are disposed on a contiguous surface of the substrate (Column 8, lines 1-21 and Fig. 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rava et al (U.S. Patent No. 5,545,531, issued 13 August 1996) in view of Schembri et al (U.S. Patent No. 6,258,593 B1, filed 30 June 1999).

Regarding Claims 13-15, Rava et al disclose a scanning system for scanning a plurality of microarray disposed on a substrate comprising: a scanner apparatus constructed and arranged to detect emission signals from the substrate; a convertible processing apparatus including a containing member (i.e. disc cartridge with mini-clamps) constructed and arranged to contain the substrate and a separating member (i.e. body containing channels which forms wells when placed on the substrate) which is constructed and arranged so that when the separating member is disposed in a first position (i.e. on the substrate) with respect to the containing members, at least two of the microarrays are fluidically separated from each other

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by the separating member and when the separating member is in a second position with respect to the containing members the at least two arrays are fluidically coupled with each other (Column 5, lines 16-65) wherein the substrate comprises a plurality of microarrays (Column 8, lines 1-5) but they are silent regarding the structure of the holder. However, substrate holders comprising first and second segments were well known in the art at the time the claimed invention was made as taught by Schembri et al. Specifically, Schembri et al teach a similar substrate comprising substrate holders wherein the holders comprise first and second segments (i.e. housing and base) wherein the substrate is disposed between the segments (Claim 13); wherein the separating member is disposed between the first and second segments when the separating member is in the first position and is disposed apart from the first and second segments when the separating member is in the second position (Claim 14); and wherein the substrate is retained in place by the first and second segments (Claim 15)(Column 11, lines 9-52 and Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the substrate holder comprising first and second segments of Schembri et al to the substrate holder of Rava et al based on the teaching of Schembri et al wherein the first and second segments form a reusable reaction chamber with the substrate wherein mixing of reaction components is facilitated, reaction contamination is reduced and evaporation is prevented (Column 4, lines 26-37). Therefore, one skilled in the art would have been motivated to apply the reaction chamber of Schembri et al to the substrate holder of Rava et al for the obvious benefits of convenience and increased quality of reaction results as taught by Schembri et al (Column 4, lines 26-37).

Response to Arguments

7. In papers filed 17 January 2003, Applicant traverses the above rejection. However, the papers filed 17 March 2003 claim priority as a continuation to the '531 patent which suggests that Applicant acknowledges that the '531 patent completely discloses the instant claims. Because the claim for priority is improper. The rejection is maintained. Applicant's

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arguments presented in the papers filed 17 January 2003 are deemed moot in view of the papers filed 17 March 2003.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 2-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,981,956.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a scanning system comprising an apparatus for detecting emission signals from a substrate, containing members to contain the substrate, an excitation source, a focusing system, a data acquisition system, a computer and translation stage. Both sets of claims differ only in the instant claims recite scanning a plurality of microarrays and detecting emission from at least two of the plurality of microarrays. While the patent claims recite "substrate" (Claims 1-25) and do not recite a plurality of microarrays, the patent teaches a substrate encompasses a plurality of arrays on a surface (Column 15, lines

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56-60). Therefore, the patent's claimed substrates encompass a surface having a plurality of arrays. As such, the instantly claimed substrate comprising a plurality of microarrays is obvious in view of the patent substrate teaching.

10. Claims 2-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,207,960 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a scanning system comprising an apparatus for detecting emission signals from a substrate, containing members to contain the substrate, an excitation source, a focusing system, a data acquisition system, a computer and translation stage. The sets of claims differ only in the instant claims recite scanning a plurality of microarrays and detecting emission from at least two of the plurality of microarrays. While the patent claims recite "substrate" (Claims 1-25) and do not recite a plurality of microarrays, the patent teaches a substrate encompasses a plurality of arrays on a surface (Column 15, lines 63-67). Therefore, the patent's claimed substrates encompass a surface having a plurality of arrays. As such, the instantly claimed substrate comprising a plurality of microarrays is obvious in view of the patent substrate teaching.

11. Claims 2-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,025,601 in view

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of Stern (U.S. Patent No. 5,981,956, issued 9 November 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a scanning system comprising an apparatus for detecting emission signals from a substrate, containing members to contain the substrate, an excitation source, a focusing system, a data acquisition system, a computer and translation stage. The claim sets differ only in the instant claims recite scanning a plurality of microarrays and detecting emission from at least two of the plurality of microarrays. While the patent claims recite support having a sample (Claims 1-18) and do not recite a plurality of microarrays, a support having a sample wherein the sample comprises a plurality of microarrays was well known in the art at the time the claimed invention was made. Specifically, Stern teaches a similar scanning system comprising support having a plurality of microarrays and they teach the plurality of microarrays on a single support is a useful for scanning multiple arrays simultaneously (Column 15, lines 56-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the support having multiple microarrays as taught in the '956 patent to the '601 support to thereby provide multiple microarrays on the support for the obvious benefits of scanning convenience as taught in the '956 patent (Column 15, lines 56-61).

Response to Arguments

12. Applicant traverses the above rejections under because none of the patents teach or suggest a convertible processing apparatus including one or more containing members arranged to contain a substrate and a separating member having a first a second position.

The argument has been considered but is not found persuasive for the following reasons:

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The '956 patent claims the containing members (Claim 2) which are described within the specification (Column 16) to meet the limitations of the instant claims i.e. have a first and second position to fluidically couple and separate microarrays.

The '601 patent claims the containing members (Claim 20) which are described within the specification (Column 12, line 45-Column 14, line 23) to meet the limitations of the instant claims i.e. have a first and second position to fluidically couple and separate microarrays.

The '960 patent claims the containing members (Claim 20) which are described within the specification (Column 16) to meet the limitations of the instant claims i.e. have a first and second position to fluidically couple and separate microarrays.

Prior Art

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. Kreek et al (U.S. Patent Application Publication No.2001/0053849 A1, filed 16 June 1999) teach a system for scanning a plurality of microarrays (§ 69-74).

b. Perov et al (U.S. Patent No. 6,407,395 B1, filed 29 February 2000) teach a system of scanning a plurality for microarrays (Column 3, lines 17-60).

c. Hang et al (U.S. Patent Application Publication No. 2002/0046712 A1, filed 1 March 2000) teach a system of scanning a plurality for microarrays (§ 57, 58 and 68).

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14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
August 4, 2003